

Atty Dkt. No.: STAN130
USSN: 09/716,841

REMARKS

In view of the above amendments and the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 16-17, 21-23, 26-28, 31-32, 51-52, 55-57, 60-62 and 65-66, the only claims pending and under examination at this time.

The undersigned thanks the Examiner for the helpful interview held on November 5, 2003. During the interview, the above amendments concerning limiting binding of the modulating moiety to an intracellular protein were discussed, and the Examiner indicated that these amendments may overcome certain of the rejections in the office action. In addition, the filing of a 132 declaration and a Terminal Disclaimer was discussed.

Claims 16, 23, 32, 51, 57 and 62 have been amended to incorporate the limitations of dependent claims in which the modulating moiety binds to an intracellular protein, and the corresponding dependent claims have been canceled. In addition, Claims 21, 26, 31, 55, 60 and 65 have been amended to clarify the claim language. As the above amendments add no new matter, their entry by the Examiner is respectfully requested.

It is noted that these amendments have been made solely in order to expedite allowance of the present application and should in no way be construed as an agreement by the Applicants with the Patent Office that claims of broader scope, including embodiments where the modulating protein binds to an extracellular protein, are not patentable to the Applicants. The Applicants expressly reserve the right to pursue claims of such broader scope in a continuation application.

Turning now to the rejections presented in the Office Action, Claims 21, 26, 31, 55, 60 and 65 were rejected under 35 U.S.C. § 112, 2nd ¶. In view of the above

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amendments, it is respectfully submitted that this rejection may be withdrawn.

Next, Claims 16, 17, 19-22 and 51-66 have been rejected under 35 U.S.C. § 102 (e) as anticipated by U.S. Patent No. 6,372,712. In view of the enclosed Declaration by Thomas Wandless, this rejection may be withdrawn.

Next, the rejection of Claims 16, 17, 19-32 and 51-66 under 35 U.S.C. 103(a) as being obvious over Nygren and Pouletty was maintained.

As amended, the claims are limited such that the modulating moiety is one that binds to an intracellular protein. As will be apparent from the below remarks, the combined teaching of Nygren and Pouletty fails to teach or suggest a bifunctional molecule in which the modulating moiety is an intracellular protein.

Nygren actually discloses large fusion proteins of a first protein domain that exhibits a desirable activity (e.g., tPA, hGH, IFG-I, IFG-II, TNF, EFG, insulin, relaxin) and a second serum protein targeting domain (e.g., an albumin binding domain). These fusion proteins therefore include a modulating moiety that binds to an extracellular protein, not an intracellular protein.

Similarly, Pouletty discloses bifunctional molecules that are conjugates of two different antibodies or specific binding fragments thereof, i.e., a first antibody that specifically binds to a blood borne agent, e.g., a drug of abuse, and a second antibody that specifically binds to long lived blood protein, e.g., serum albumin. As such, Pouletty's modulating moiety is also a moiety that binds to an extracellular moiety.

As characterized by the Examiner and shown above, both Nygren and Pouletty are limited to bifunctional compounds that bind to extracellular proteins, e.g., serum albumin. Neither Nygren nor Pouletty teach or suggest a bifunctional molecule that includes a modulating moiety that binds to an intracellular moiety.

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Accordingly, Claims 16, 17, 19-32 and 51-66 are not obvious under 35 U.S.C. 103(a) over Nygren and Pouletty and this rejection may be withdrawn.

Finally, Claims 16, 17, 19-32 and 51-66 have been rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,372,712 and provisionally rejected under the judicially created doctrine of obviousness-type double patenting over Application No. 9/025,930. In view of the enclosed Terminal Disclaimer, this rejection may be withdrawn.

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CONCLUSION

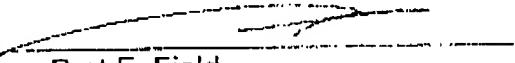
In view of the above amendments and remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815.

Respectfully submitted,

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Date: 12-18-03

By: 

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encs:

Wandless Declaration
Terminal Disclaimer

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